PSJ4 SOL Opp Exh 6

HDMA POSITION STATEMENT

DEA RULES AND ENFORCEMENT: "SUSPICIOUS ORDERS" MONITORING

HDMA's Position

HDMA supports "suspicious orders" monitoring and reporting as an important component of addressing the serious issue of the misuse and diversion of controlled substances. HDMA recognizes that increased abuse and diversion of controlled substances threaten patient safety and the security of the healthcare supply chain. Distributors — along with manufacturers, pharmacies and healthcare practitioners — share a mission and responsibility to continuously monitor, protect and enhance processes and practices to reduce the diversion of controlled substances.

HDMA proactively developed the *HDMA Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances* to support distributors' ongoing commitment to the safe and efficient distribution of all prescription medicines, including controlled substances. These Industry Compliance Guidelines (ICG) are consistent with, and further extend, distributors' track record of supporting and implementing initiatives to improve the safety, security and integrity of the healthcare supply chain.

Issue

The U.S. healthcare supply chain is one of the most secure and sophisticated in the world, routinely enabling the safe and efficient delivery of medicines. At the center of this supply chain, distributors are uniquely positioned to perform due diligence to help support the security of the controlled substances they deliver to their customers. This can help ensure that those who purchase controlled substances from distributors intend to dispense them for legally acceptable purposes.

Additional Information

HDMA has met with and received constructive feedback from the Drug Enforcement Administration (DEA) on the ICG. DEA has issued a letter to HDMA commending the industry on its effort, noting that "…companies that implement processes and procedures that effectively accomplish these objectives will do much to ensure that vital controlled substances are not diverted to illegitimate uses." HDMA and its members will continue to take a leadership role to address this important issue.

For more information, refer to:
http://www.healthcaredistribution.org/gov_affairs/pdf_controlled/20081113_icg.pdf and
http://www.healthcaredistribution.org/gov_affairs/pdf_controlled/20081113_dealetteronicg.pdf

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HDMA POSITION STATEMENT

DRUG DISPOSAL

HDMA's Position

HDMA supports efforts to ensure the safe and secure disposal of unused, unwanted or expired medications. HDMA advocates for ensuring patient privacy and safety, preventing diversion, streamlining standards for disposal and destruction of controlled substances and preserving a safe and efficient system for pharmaceutical distribution. Congress must consider the complexity of the regulatory environment and the multiple agencies involved in establishing disposal standards and guidelines for controlled substances — such as the Environmental Protection Agency (EPA), the Drug Enforcement Administration (DEA), the Food and Drug Administration (FDA) and other regulatory entities — as well as the importance of maintaining a secure system to prevent diversion.

Issue

The DEA oversees the prescribing, delivery and distribution of prescriptions covered by the Controlled Substances Act (CSA), but the CSA is largely silent on how patients can properly dispose of their medications. This has led to growing concern about the vulnerability of the supply chain toward illicit diversion and the potential environmental effects of disposing controlled substances by current prescribed methods.

Existing mechanisms by which to dispose drugs include:

- Flushing unused medication; while recommended in the past, more recent analysis has shown that depositing the drugs into the water supply may pose a potential environmental hazard;
- Throwing away unused medication; this is a process by which consumers are encouraged to coat the leftover pills in cat litter or coffee grounds to make them less appealing for diversion; and,
- Returning drugs through DEA-approved take-back programs; these are limited by current law to law enforcement agencies that have obtained a waiver from DEA to take custody of unused controlled substances.

Congressional efforts to improve consumers' knowledge of and adherence to proper disposal methods, particularly for controlled substances, have led to proposals to authorize additional entities to accept unused, expired or unwanted medications for disposal. Additionally, recently passed but not yet implemented legislation expands the DEA's authority to determine a proper disposal venue and tasks various other entities to study current drug-disposal mechanisms.

Additional Information

HDMA remains committed to ensuring the safety and integrity of the healthcare supply chain by enhancing public safety through increased consumer education on proper drug disposal methods.

HDMA supported the Secure and Responsible Drug Disposal Act of 2010, which was signed by President Obama on October 12, 2010, to become Public Law 111-273.

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HDMA POSITION STATEMENT

IMPACT OF GROSS RECEIPTS TAX ON PHARMACEUTICAL DISTRIBUTORS

HDMA's Position

Efforts by state governments to change existing tax laws to impose a gross receipts tax on the pharmaceutical distribution industry is inherently inequitable due to the unique high-value, low-margin nature of the business. The application of a multi-tiered tax will make medicines less affordable, ultimately disrupting state efforts to contain healthcare costs. HDMA instead supports providing alternative tax options, such as a gross margins tax or a business income tax for distribution industries, which are disproportionately affected by a tax on gross receipts.

- Distributors' revenues are almost entirely and immediately offset by the costs of purchasing medicines, resulting in razor-thin profit margins. A gross receipts tax is not a tax on profit, but is a tax based on total sales revenue without consideration of operating costs or expenses (cost of medicine) or profit.
- A gross receipts tax has a significant financial impact on pharmaceutical distributors given the high dollar value of the products they carry. For example, even if the gross receipts tax rate is relatively low, the total tax owed becomes substantial when multiplied by the high volume and value of pharmaceutical products sold by distributors. The unique distribution business model will result in a disproportionately high tax, compared with other industries.

Issue

Pharmaceutical distribution is an industry that suffers disproportionately from a gross receipts tax. For distribution companies operating in such a highly competitive market, it is impossible to absorb the negative financial impact of a gross receipts tax the way that other industries can. For example, at a national level, a 0.25 percent gross receipts tax would average 2.8 percent of pre-tax income for all industries. By contrast, within the healthcare distribution sector, the tax burden would be equivalent to 17.9 percent of pre-tax income – *almost six times higher than the average industry*. Applying gross receipts taxes on medicines will compound costs throughout the healthcare supply chain, likely increasing the costs of medicines for patients.

Additional Information

The application of a gross receipts tax on medicine will have a cumulative impact throughout the healthcare supply chain, as the same medicines would be taxed multiple times before reaching the consumer:

- At the time of sale by the manufacturer to the distributor;
- When sold by the distributor to the pharmacy; and,
- In many states, when sold by the pharmacy to the consumer.

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HDMA POSITION STATEMENT

IMPORTATION OF PRESCRIPTION MEDICINES

HDMA's Position

HDMA is opposed to permitting the commercial or personal importation of pharmaceuticals into the United States. Importation, whether restricted to Canada or a select list of other countries, significantly increases the likelihood of counterfeit or adulterated prescription medicines entering the U.S. marketplace and places U.S. patients at risk.

Issue

The Department of Homeland Security Fiscal Year (FY) 2011 budget includes a provision to allow individuals to hand carry a 90-day supply of a prescription drug from Canada, excluding controlled substances and biologics. The same provision existed under the Homeland Security FY 2010 budget.

However, patients can be placed at risk due to the presence of counterfeits in other countries and the fact that Internet purchasing often hides the true origin of products. For example, according to the World Health Organization (WHO), more than 30 percent of prescription medicines can be counterfeit in many Latin American, African and Asian countries. The WHO also found that purchases from illegal Internet sites are counterfeit more than half the time.

In the United States, 87 percent of prescription medicines sold are stored, managed and delivered by HDMA member companies. HDMA members serve as a vital link in the healthcare supply chain by ensuring product integrity and providing the highest-quality medicines and services, ensuring that costs are as low as possible and enabling providers to deliver care more effectively to patients. Patient safety and product integrity will suffer as a result of prescription medicine importation.

Additional Information

- HDMA does not support commercial importation of medicines whether by wholesale distribution companies, pharmacists or individuals.
- Limiting personal or commercial importation from a specific country or countries does not diminish the likelihood of counterfeit or adulterated drugs entering the U.S., nor will it assure significant reductions in the costs of prescription drugs.
- HDMA members have serious concerns that imported prescription medicines may not have been properly stored and handled, and that they may have been tampered with or mislabeled.

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HDMA POSITION STATEMENT

LICENSING HEALTHCARE DISTRIBUTORS

HDMA's Position

HDMA strongly supports tough, rigorous and consistent standards for state licensing of healthcare distributors as required under federal law. Having strong, consistent distributor licensing is a critical component to ensure that criminals do not infiltrate the supply chain and gain access to prescription medicines. HDMA continues to work with supply chain partners and state and federal officials to develop uniform legislation and regulations pertaining to licensure.

Specifically, HDMA advocates for the following licensure requirements that will help deter and prevent the infiltration of counterfeit drugs into this industry:

- Stringent application requirements;
- Pre-licensure and regular inspections;
- Surety bonds;
- Criminal background checks;
- Stronger penalties; and,
- Technological solutions to pedigree.

Issue

The introduction of counterfeit or adulterated medicines into the supply chain is a serious issue that could adversely affect the safety of prescription medicines and the health of patients. HDMA and its member companies support uniform licensing standards that prevent the entry of unscrupulous or criminal elements, address the roles and responsibilities of distributors in the supply chain and provide accountability for their business practices. We are committed to a business model that maintains the safety and integrity of the prescription drug products that patients depend on for their health and well-being.

Additional Information

HDMA has proactively worked with all 29 states that have strengthened their distributor licensure requirements in recent years. However, each state has focused on different aspects of this critical issue and there is little uniformity in bills or regulations across the states.

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HDMA POSITION STATEMENT

LIFO REPEAL

HDMA's Position

HDMA opposes the repeal of the last-in, first-out (LIFO) inventory accounting method. Eliminating the ability to elect the LIFO method would have a grossly disproportionate impact on pharmaceutical distributors due to their inventories of high-volume, high-value medications. Its repeal would reverse long-standing tax policy and result in an unprecedented tax increase for these companies.

- HDMA member companies distribute 87 percent of all prescription medicines dispensed in the U.S. Repealing the LIFO election would significantly impact their viability and would likely result in an increase in the cost of prescription drugs for Americans.
- According to a 2010 study on tax accounting for the pharmaceutical distribution industry, the ongoing tax increase resulting from repeal of the LIFO election would increase annual federal income tax liability within the pharmaceutical distribution industry by an estimated 51.8 percent—nearly three times more than the average industry. This is particularly challenging in an industry that, according to historical aggregated data, has an exceptionally low net-profit margin of only 1.1 percent.
- Repealing LIFO would force companies currently using this accounting method to report their LIFO reserves as income, resulting in a massive retroactive tax increase for companies without a corresponding economic benefit.
- HDMA distributor members use LIFO because it provides a better method to measure financial performance and calculate tax liability as inventory costs continue to rise. LIFO takes into account the greater costs of replacing inventory, thereby giving a more accurate measure of both the financial condition and the taxable income of a business.

Issue

LIFO has been an established and recognized accounting method in the U.S. since the 1930s and is used for tax-reporting purposes by a broad spectrum of business sectors that sell a wide range of products. Elimination of LIFO would be particularly punitive on distributors of high-value products such as pharmaceuticals. The repeal of LIFO would increase taxes for distributors in two ways:

1. **Recapture Tax:** This retroactive increase in taxable income is estimated to be the equivalent of four years of normal corporate tax payments for the pharmaceutical distribution industry, in comparison to an average of two years for other industries.
2. **Ongoing Tax:** The annual increase in taxable income liability for the pharmaceutical distribution industry is estimated to be 51.8 percent, an increase in excess of three times more than the average industry.

Distributors Provide Savings to the Healthcare System

Healthcare distributors ensure that nearly nine million prescription medicines and healthcare products are safely delivered to nearly 200,000 pharmacies, hospitals, nursing homes, physician offices, clinics and others nationwide. With nearly 170 distribution facilities across the country, our members provide jobs, significantly contributing to the local economy in which they are located.

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HDMA POSITION STATEMENT

MARKETING AND GIFT RESTRICTIONS

HDMA's Position

There is increasing interest among lawmakers to require pharmaceutical manufacturers to disclose their marketing activities related to prescription medicines. The intent of such legislation is to make transparent the relationships between pharmaceutical manufacturers and the physicians or other health professionals who prescribe medications.

For the following reasons, HDMA believes that gift disclosure legislation should not include requirements applicable to distributors:

- Healthcare distributors should not be subject to the same gift and marketing reporting requirements as pharmaceutical manufacturers because healthcare distributors do not influence the selection of medicines by physicians and other healthcare providers. Instead, they fulfill the orders provided by pharmacists, physicians and other healthcare professionals.
- Distributor marketing focuses only on the services that distributors provide — e.g., the ability to fulfill the medical decisions of healthcare providers — not to influence which products they choose.
- A distributor exemption from legislation proposed to address marketing and gift restrictions would provide a clear distinction between manufacturers (who may market and distribute their own products to healthcare professionals) and state-licensed, primary healthcare distributors (who provide services regardless of the products healthcare professionals select and so do not influence product selection).

Issue

Pharmaceutical manufacturers expend significant resources to educate healthcare providers, hospitals and health benefit plan administrators about their pharmaceutical products. As a result, many legislators have introduced legislation that would require pharmaceutical manufacturers to disclose any gifts given to healthcare providers or others who are responsible for selecting the brand or type of medicine that they will prescribe or provide to patients.

Some gift disclosure legislation that has been introduced would impose the same reporting requirements on healthcare distributors as on pharmaceutical manufacturers, despite the fact that the role of the healthcare distributor in the pharmaceutical supply chain is vastly different than that of the manufacturer.

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HDMA POSITION STATEMENT

MEDICARE AVERAGE SALES PRICE

HDMA's Position

HDMA believes customary prompt pay discounts extended by manufacturers to distributors should be excluded from the manufacturers' calculation of the Average Sales Price (ASP) for Part B drugs and biologics. Prompt pay discounts are based on negotiated terms between the manufacturer and the distributor for payment within a certain time frame and represent the time value of money. These discounts are typically not passed on to the physician purchasing the product. Excluding prompt pay discounts would align Medicare reimbursement with current Medicaid reimbursement methodology, which excludes prompt pay discounts from the calculation of Average Manufacturers Price (AMP) and ensures fair and accurate reimbursement for physicians and clinics.

Issue

The Medicare Prescription Drug Improvement and Modernization Act (MMA) of 2003 established ASP as the reimbursement metric for drugs reimbursed under Medicare Part B. Part B drugs or specialty pharmaceuticals — many of which are biologically derived — are used primarily to treat chronic or rare diseases, typically involve treatment regimens that call for ongoing clinical monitoring and patient education, and frequently require special handling, storage and delivery. In the 2006 Physician Fee Schedule (PFS) (CMS-1321-FC) CMS interpreted the MMA definition of ASP to include prompt pay in the calculation of ASP. HDMA disagrees with CMS interpretation and believes CMS has the legal authority to instruct manufacturers to exclude the deduction of customary prompt pay discounts to wholesalers from ASP.

Failure to exclude prompt pay discounts from the calculation of ASP threatens the current distribution model for specialty products and artificially lowers Part B reimbursement for physicians and other providers.

- Physicians receive an artificially lower reimbursement which could affect access to critical care for patients with complex and life-threatening diseases like cancer.
- Manufacturers may have an incentive to bypass distributors in order to prevent lower reimbursement rates for their physician customers. This is a concern because the current distribution channel provides supply chain services in the most cost-efficient manner, saving the health care system $32 billion a year. Currently distributors:
    - Eliminate the need for manufacturers to replicate delivery and handling process;
    - Streamline processing for more than 10,000 physicians through consolidated ordering, billing and delivery; and,
    - Promote product integrity for consumers.

Additional Information

HDMA supports efforts to exclude customary prompt pay discounts from the calculation of ASP, including the following legislation:

- H.R. 905, introduced by Rep. Ed Whitfield (R-Ky.) and Rep. Gene Green (D-Texas); and,
- S. 733, introduced by Senator Debbie Stabenow (D-Mich.) and Senator Pat Roberts (R-Kan.)

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HDMA POSITION STATEMENT

CREDIT FOR RETURNS

HDMA's Position

HDMA believes that the government should not require prescription drug distributors to accept returns of either full or partial expired prescription drugs for prompt full credit or replacement. The returns processes for expired, non-salable prescription drugs, including associated credit policies, are generally dictated by the product's manufacturer — not the distributor — and are subject to the manufacturer's requirements.

Requiring distributors to bear the full costs of providing full credit or replacement for outdated prescription medicines would be costly and result in numerous inequities, including:

- Creating conflicts with trading agreements and contracts already established by manufacturers for crediting expired products;
- Placing an unjust burden upon the distributor – as opposed to the manufacturer – for returns compensation, despite the fact that the manufacturer sets the returned goods policies; and,
- Increasing the volume of opened drug containers (partials) being shipped for return, which could increase the risk of diversion, fraud or the introduction of counterfeit medicines.

Issue

HDMA agrees that an efficient prescription returns process is an important and necessary practice for pharmacies and distributors in such cases as ordering errors and unusable products. Processes for *salable* returns often are dictated by agreements between distributors and their pharmacy customers. By contrast, however, returns processes for *non-salable* or *expired* prescription medicines, including providing credit, are generally dictated by the product manufacturer.

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HDMA POSITION STATEMENT

STATE CONTROLLED SUBSTANCE SALES REPORTING

HDMA's Position

As an advocate for the safe, reliable and efficient distribution of the nation's healthcare products, HDMA supports wholesaler reporting requirements that remain consistent with existing federal requirements. HDMA shares the objective of state legislation that seeks to combat the problems associated with prescription drug abuse. HDMA and its members have a history of supporting rigorous standards for the pharmaceutical supply chain at both the federal and state level.

While we support the intent of such legislation, it should not require wholesalers to report sales of controlled substances that are not part of the current DEA Automation of Reports and Consolidated Orders System (ARCOS) reportable products and that are in a format that is inconsistent with current federal ARCOS reporting.

Issue

ARCOS is an automated reporting system that tracks Schedule II and some Schedule III narcotic controlled substances from the manufacturer through distribution to the dispensing/retail level. According to the DEA, more than 30 million transactions are reported each year by roughly 1,100 distributors and manufacturers; the reports are used by DEA and other federal, state and local investigative agencies to identify the diversion of controlled substances into illicit channels of distribution and the dispensing/retail level.

Some state legislation proposes the establishment of reporting requirements that are not consistent with the types of controlled substances already reported by wholesalers to the DEA and the format by which they are reported. Conflicting reporting requirements would cause wholesalers to significantly change and reformat their current systems to something other than what is now in use and readily available with the DEA requirements. If every state created a different set of reporting requirements, wholesalers would be required to follow a patchwork of 50 different rules and regulations when one, uniform and less costly example of how to address this issue has existed within the DEA for years.

In addition, instead of capitalizing on DEA's current information system, states would have to invest in and create their own complex information technology systems. This would require hiring staff capable of receiving, maintaining and analyzing the significant amounts of sales data that will be received from each wholesaler licensed with the state. It also may benefit the state to make inquiries to DEA to determine if the state can have access to data already presented into federal ARCOS. This would result in substantial savings to the state in potentially significant infrastructure costs while obtaining the data desired.

Again, for the reasons stated above, if the state is unable to obtain relevant information directly from DEA, HDMA recommends allowing for reports of wholesaler sales of controlled substances that are consistent with the DEA ARCOS requirements.

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HDMA POSITION STATEMENT

STATE LICENSING OF PAIN MANAGEMENT CLINICS

HDMA's Position

In recent years there has been an emergence of some pain management clinics operating as "pill mills." These types of clinics inappropriately dispense drugs that have the highest potential for abuse and diversion with little or no medical examinations. The rise in these clinics has directly contributed to the increase in prescription drug abuse across the country. The appropriate state licensing of pain management clinics is another tool for state law enforcement officials to use when coordinating investigations with federal and local authorities; HDMA supports the state licensing of pain management clinics.

When developing such laws, efforts must be made to ensure that legitimate medical clinics can continue to operate and deliver necessary care to patients. HDMA and its distributor-member companies have a history of working with supply chain partners and state and federal officials to develop stronger licensing requirements for distributors.

Specifically, HDMA supports the following licensure requirements pain management clinics:

- Ownership by a doctor registered with the state;
- Initial inspections prior to licensure and regular annual inspections thereafter;
- A prohibition for dispensing more than a 72-hour supply for patients who pay with cash, check or credit card instead of insurance;
- Significant criminal penalties for knowingly operating, owning or managing a non-registered pain management clinic that is required to be registered with the state; and,
- Preemption of local jurisdictions from licensing pain clinics.

Issue

Pain management clinics operating as "pill mills" often elude law enforcement by disguising themselves as another type of clinic or office. These types of clinics also are known to open and close abruptly to avoid the authorities. While the problem has been seen across the country, evidence has shown that they are most prevalent in Florida and Texas. In Florida's Broward County alone the County Sheriff's Office reported in 2010 that more than one million tablets of Oxycodone, a potentially dangerous painkiller, were prescribed every month in the county. In addition, they reported that 38 of the 50 doctors who prescribe the most Oxycodone in the United States are located in Broward County.

Additional Information

In 2010 Florida became the first state to enact legislation requiring the licensure of pain management clinics. The new law provides the Department of Health the authority to regulate pain management clinics that prescribe or dispense controlled substances. Ohio and Tennessee enacted similar legislation in 2011.

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HDMA POSITION STATEMENT

STATE PRESCRIPTION DRUG MONITORING PROGRAMS

HDMA's Position

HDMA supports continued federal funding of state prescription drug monitoring programs (PDMPs). With states across the country still facing record budget deficits, federal funding of PDMPs is critical. A PDMP is an electronic database that collects statewide dispensing and prescribing data on specified substances. The data is held by a state regulatory, administrative or law enforcement agency. PDMPs are used by states as a tool to identify and prevent prescription drug abuse and diversion. Pharmaceutical distributors, while not prescribing or dispensing controlled substances, work nationwide with state and federal officials and industry partners to ensure product availability while minimizing opportunities for diversion.

Currently, there are two federal sources of funding for PDMPs: the Harold Rogers Prescription Drug Monitoring Program (HRPDMP) and the National All Schedules Prescription Electronic Reporting Act (NASPER). HRPDMP is administered by the U.S. Department of Justice and provides for planning, implementation, and enhancement grants. NASPER is administered by the U.S. Department of Health and Human Services (HHS), and funds PDMP databases.

Issue

The dramatic rise of prescription drug abuse has achieved epidemic proportions across the country in the last ten years. In 2010, HHS reported that between 1998 and 2008, hospital admissions for abuse of prescription pain relievers increased by 400 percent. The White House Office of National Drug Policy recently reported that prescription pain killers are now the second most abused drug in the country. Other commonly abused types of prescription drugs include tranquilizers, stimulants and sedatives. To combat the potential for diversion or abuse of controlled substances, many states use PDMPs to track drugs through the patient, prescriber or dispenser to ensure that their prescribing and dispensing is appropriate.

Additional Information

As of September 2011, 37 states have operational PDMPs with the capacity to receive and distribute controlled substance prescription information to authorized users. States with operational programs include: Alabama, Arizona, California, Colorado, Connecticut, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Montana, Nevada, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Vermont, Virginia, West Virginia and Wyoming.

Eleven states — Alaska, Arkansas, Delaware, Florida, Georgia, Maryland, Nebraska, New Jersey, South Dakota, Wisconsin and Washington — have enacted legislation to establish a PDMP, but are not fully operational.

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HDMA POSITION STATEMENT

UNIFORM FEDERAL PEDIGREE

HDMA's Position

HDMA supports enacting a uniform federal pedigree requirement as a necessary step to further enhance the security of the nation's prescription medicine supply chain. A practical and comprehensive approach at the federal level will increase safety, facilitate efficient interstate commerce and minimize the inconsistencies among competing state requirements. National uniformity will enable manufacturers, distributors and pharmacies to:

- Help combat threats to the safety of the supply chain;
- Utilize the most effective technologies to help stop counterfeiting and diversion of prescription medicines; and
- Facilitate efficient interstate commerce.

Issue

The "Prescription Drug Marketing Act (PDMA) of 1987" established minimum federal pedigree requirements to trace the ownership of pharmaceuticals through the supply chain. The purpose of PDMA was to further secure the nation's medicine supply from counterfeit and diverted prescription medicines.

However, state regulatory authorities have wide latitude to expand both licensure and pedigree requirements as long as they meet the current minimum federal thresholds. In recent years, more than half of the states have imposed new and inconsistent pedigree requirements for manufacturers, distributors and pharmacies or other authorized dispensers. The resulting patchwork of state-level requirements creates confusion and duplicates resources, particularly for national and regional companies. Moreover, since PDMA was enacted more than 20 years ago, the pharmaceutical industry has significantly evolved in the manufacture, distribution and dispensing of prescription medicines. This has added considerable complexity to regulatory compliance while meeting today's healthcare needs.

Additional Information

HDMA believes in the following principles for federal pedigree legislation:

- A uniform, national requirement that incorporates a primary distribution (or direct-purchase pedigree) model until such time as a standard and technology solutions are reasonably available to facilitate the implementation of cost-effective electronics by manufacturers, wholesalers and dispensers (pharmacies, physicians, hospitals, clinical and other provider settings where drugs are dispensed to patients).
- Serialization of prescription drugs at the unit, case and pallet levels, along with a standardized data exchange system.
- Heightened wholesaler licensure requirements.
- Penalties for pharmaceutical related crimes such as cargo theft, illegal importation, fraud and abuse.

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